REMARKS

I. Status of the claims

In response to the Office Action dated August, 18 2010, Applicants respectfully request consideration of the claims provided herein. Claims 54, 57-60, 69, 84, 85, 97, 98, 111, 112, 117, 123, 124, 136-138, 148, 149, 152, 154, 155, and 160 are pending. Claims 53, 55, 61, 63, 66-68, 71-73, 78-80, 83, 89, 91, 93-96, 99-101, 106-108, 110, 116, 118, 120-122, 125-127, 132-134, 139-147, 153, 157-159, 162-164, and 169-171 are amended. New claims 172-176 are added. Claims 1-52, 56, 62, 64, 65, 70, 74-77, 81, 82, 86-88, 90, 92, 102-105, 109, 113-115, 119, 128-131, 135, 150-151, 156, 161, and 165-168 are cancelled.

II. Support for the amendments

The amendments provided herein do not constitute new matter. Support for the amended and new claims can be found in the claims and specification as filed including, *inter alia*, in the claims as originally filed. Cancellation of any subject matter herein does not constitute an admission that the subject matter is unpatentable for any reason.

Basis for new claims is found in the specification and the claims as filed for the parent case. For example, basis for new claims 172 and 173 can be found at least in claims 72, 100, 126, and 163. Basis for new claim 174 can be found at least in claims 73, 101, 127, and 164. Basis for new claim 175 can be found at least in claims 78, 106, 132, and 169. Basis for new claim 176 can be found at least in claims 80, 108, 134, and 171.

III. Interview Summary

Applicants' appreciate the courtesy extended to them by the Examiner during the interview on February 16, 2011 with Applicants representatives, Louis D. Lieto and Esther Kepplinger. During the interview the outstanding rejections and claims were discussed.

IV. Double Patenting

Claims 53-55, 57-61, 63, 66-69, 71-73, 78-80, 83-89, 91, 93-101, 106-108, 110-112, 116-118, 120-127, 132-134, 136-149, 152-155, 157-160, 162-164, and 169-171

were rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-14 of U.S. Patent No. 6,632,429 in view of Beck et al. (US 6,020,310, provided by applicants) and Bode et al. (Clin Biochem. 1986;19:333-37; of record), and as evidenced by Schreck & Williams (Res Dev Disabil. 2006; 27:353-363). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Applicants submit that the Examiner's double patenting rejection relies on the assertion that:

> With respect to the limitation reciting that the individual has a self limiting diet consisting primarily of carbohydrates, this behavior is characteristic of autistic individuals and would necessarily be present in the population being treated (e.g., autistic children). For example Schreck & Williams evidence that children with autism preferentially consume foods with high sugar content (i.e., high in carbohydrates)...Hence treatment of autistic children in general would encompass, and therefore render obvious, the treatment of autistic individuals having a carbohydrate-rich diet. (Pg. 6, Office Action 8/18/2010) (Emphasis added)

Applicants note that the Examiner solely relies on Schreck & Williams to support her characterization of autistic individuals. Further, as Schreck & Williams was published in 2006, after the filing date of the instant application, it is not available as a primary reference against the pending claims. The Examiner is aware of this as she has asserted the reference as extrinsic "evidence" in support of her primary references. However, the MPEP limits the kind of references that can be used as evidence to show an inherent characteristic of a thing taught by the primary reference. *See* MPEP 2131.01 (III). The relevant portion of the MPEP states:

> "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). (MPEP 2131.01 (III)) (Emphasis added)

Applicants submit that Schreck & Williams does not rise to the level of disclosing that "a self limiting diet consisting primarily of carbohydrates" is necessarily present in

the population of autistic individuals to be treated. Applicants note that Schreck & Williams states: "[r]esults indicated that the children preferred fewer types of food items within groups than their families; however, family food preferences appeared to influence food selection more than the diagnostic characteristic of autism." (Abstract, Schreck & Williams,) (Emphasis added). Further, Schreck & Williams states: "this study did not find any evidence in support of the commonly held assumptions that the feeding selectivity of children with autism could be related to their autism symptoms." (Pg. 360, Schreck & Williams) (Emphasis added). Applicants submit that these statements clearly indicate that Schreck & Williams' findings do not establish that that "a self limiting diet consisting primarily of carbohydrates" is a necessary characteristic of the food preferences of autistic individuals. Therefore, Applicants believe that Schreck & Williams is not eligible to be used as evidence for the proposition asserted by the Examiner.

Further, Applicants note that the pending claims are directed to treating autism in individuals that have a self-limiting diet consisting primarily of carbohydrates, not all autistic individuals. Applicants submit that none of the primary references cited, alone or in combination, disclose or provide guidance on treating autism in individuals that have a self-limiting diet consisting primarily of carbohydrates in the manner recited in the claims.

Applicants respectfully request that the double patenting rejection be withdrawn in view of the arguments above.

V. Rejection under 35 USC § 103

Claims 136-138, 142-147, 153-155, 162-164, and 169-171 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over US 6,020,310 to Beck et al. (of record) as evidenced by Schreck & Williams (Res Dev Disabil. 2006; 27:353-363), and in view of US 4,079,125 to Sipos (of record) and US 5,750,104 to Sipos (listed on IDS filed 03/04/2010).

Applicants submit that the Examiner's rejection of the claims as being unpatentable relies on the assertion that:

> As evidenced by Shreck and Williams autistic children tend to preferentially consume foods with a high sugar and/or starch content...therefore children with autism could be said to consume a diet consisting primarily of carbohydrates. (Pg. 9, Office Action 8/18/2010) (Emphasis added)

Applicants note that the Examiner solely relies on Schreck & Williams to support her characterization of autistic individuals. Further, as Schreck & Williams was published in 2006, after the filing date of the instant application, it is not available as a primary reference against the pending claims. The Examiner is aware of this as she has asserted the reference as extrinsic "evidence" in support of her primary references. However, the MPEP limits the kind of references that can be used as evidence to show an inherent characteristic of a thing taught by the primary reference. *See* MPEP 2131.01 (III). The relevant portion of the MPEP states:

> "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.,* 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). (MPEP 2131.01 (III)) (Emphasis added)

Applicants submit that Schreck & Williams does not rise to the level of disclosing that "a self limiting diet consisting primarily of carbohydrates" is necessarily present in the population of autistic children to be treated. Applicants note that Schreck & Williams states: "[r]esults indicated that the children preferred fewer types of food items within groups than their families; however, family food preferences appeared to influence food selection more than the diagnostic characteristic of autism." (Abstract, Schreck & Williams) (Emphasis added). Further, Schreck & Williams states: "this study did not find any evidence in support of the commonly held assumptions that the feeding selectivity of children with autism could be related to their autism symptoms." (Pg. 360, Schreck & Williams) (Emphasis added). Applicants submit that these statements clearly indicate that Schreck & Williams' findings do not establish that that "a self limiting diet consisting primarily of carbohydrates" is a necessary characteristic of the food preferences of autistic individuals. Therefore, Applicants believe that Schreck & Williams is not eligible to be used as evidence for the proposition asserted by the Examiner.

Further, Applicants note that the pending claims are directed to treating autism in individuals that have a self-limiting diet consisting primarily of carbohydrates, not all autistic individuals. Applicants submit that none of the primary references cited, alone or in combination, disclose or provide guidance on treating autism in individuals that have a self-limiting diet consisting primarily of carbohydrates in the manner recited in the claims.

Applicants respectfully request that the rejection of the claims as being unpatentable be withdrawn in view of the arguments above.

Claims 53-55, 57-61, 63, 66-69, 71-73, 78-80, 83-85, 89, 91, 93-101, 106-108, 110-112, 116-118, 120-127, 132-134, 139-141, 148, 149, 152 and 157-160 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over US 6,020,310 to Beck et al. as evidenced by Schreck & Williams (Res Dev Disabil. 2006; 27:353-363), and in view of US 4,079,125 to Sipos (Sipos(a)) and US 5,750,104 to Sipos (Sipos(b)) as applied to claims 136-138, 142-147, 153-155, 162-164, and 169-171 above, and further in view of Bode et al. (Clin Biochem 1986; 19:333-37; of record). The teachings of Beck as evidenced by Schreck & Williams, and in view of the Sipos references are discussed above. Briefly, the combined teachings provide for a method of treating autism in an autistic individual comprising administering a pharmaceutical composition comprising one or more digestive enzymes, including notably lipase, amylase and protease, and evaluating the efficacy of the treatment by pre- and post-assessment of autistic behaviors/symptoms, such as by using a diagnostic test (CARS).

Applicants submit that the Examiner's obviousness rejection relies on Schreck & Williams as discussed above. *See* Pg. 13, Office Action 8/18/2010. For the reasons stated above, applicants submit that Schreck & Williams is not proper evidence.

Applicants respectfully request that the rejection of the claims as being unpatentable be withdrawn in view of the arguments above.

CONCLUSION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned attorney with any questions or to otherwise expedite prosecution.

Further, none of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Respectfully submitted,

Dated: February 18, 2011 By: _____

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